

## **Pesticide Determination Requests for Microbial Products – Explanation & Information Needed**

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates substances that are intended for a pesticidal purpose (40 CFR § 152.15). A pesticide is (1) any substance (or mixture of substances) intended for preventing, destroying, repelling, or mitigating any pest; (2) any substance (or mixture of substances) intended for use as a plant regulator, defoliant, or desiccant; and (3) any nitrogen stabilizer. Before a pesticide may be sold or distributed in the U.S., it must first be registered by EPA. There are some instances where products are not considered to be pesticides or are excluded or exempted from FIFRA regulation (e.g., see 40 CFR §§ 152.6 and 152.25); thus, registration with EPA is not required. EPA's overall explanation as to how it determines whether a product is a pesticide can be found here: <https://www.epa.gov/sites/production/files/2015-03/documents/chap-02-apr-2014.pdf>.

If your product is determined not to be a pesticide but a product, like a biofertilizer, that contains an intergeneric microorganism (i.e., a microorganism where there has been the deliberate combination of genetic material originally isolated from organisms classified in different taxonomic genera or a microorganism constructed with synthetic genes that are not identical to DNA that would be derived from the same genus as the recipient microorganism), then it might be regulated by EPA under the Toxic Substances Control Act (TSCA) instead. See [https://www.epa.gov/sites/production/files/2015-09/documents/ch4-wozniak-et-al-fifra-ffdca-tsca-112012\\_0.pdf](https://www.epa.gov/sites/production/files/2015-09/documents/ch4-wozniak-et-al-fifra-ffdca-tsca-112012_0.pdf) also for more information.

We will assess your claims, the composition of your product, and the information that you provide to work towards making a determination as to whether your product is a pesticide, but we will need some additional materials to make a determination. These materials are as follows:

1. Complete compositional information of your product – Microorganism(s) (genus, species, and strain/isolate) + other ingredients = 100%. You could structure the presentation of the compositional information as follows:

<b>Product Name</b>	
<b>Ingredient (CAS Reg. No. If Applicable)</b>	<b>Percentage in Formulation</b>
<i>Genus species</i> strain/isolate	XX%
Ingredient 1 (CAS Reg. No.)	XX%
Ingredient 2 (CAS Reg. No.)	XX%
Total	100%

2. A draft label and any other advertising materials to be used besides the label (e.g., brochures and website claims) for your product. Please ensure that the label and/or advertising materials clearly describe things like how your product is going to be applied (e.g., to the soil, to the foliage of plants, or to both), the application rate, and the plants to which applications will be made.

3. Information that you may have (or know of) that shows the microorganism(s) in your product has/have non-pesticidal activity (e.g., peer-reviewed public literature, data from field trials, etc.).

To expand upon what is presented directly above, if you want to claim a significant, commercially valuable non-pesticidal benefit of "nutrient uptake" or similar, you need to provide data that directly substantiate such claims. Examples of these data are as follows:

**Field trials** from crop studies that demonstrate a significant difference between untreated control and test subjects treated with microbial agents in total uptake of micro- and/or macro-nutrients in plant biomass. These data must include relevant statistical analyses to show scientific validity.

**Lab trials** that demonstrate mineralization of one or more particular micro- or macro-nutrients. These data must include relevant statistical analyses to show scientific validity.

**Public literature** that references the exact strain and exact species of microorganism being used in the product intended for sale and/or distribution. Any submitted literature must be presented in a clear format, with highlighted (or similar) sections that demonstrate the claimed non-pesticidal benefit.

4. Confirmation as to whether the microorganism(s) in your product is/are intergeneric (description above) or naturally occurring.

Once you provide the pieces of information described above for your product, we will be able to proceed with a more thorough evaluation.

Currently, a request for EPA to make a formal pesticide determination, like you appear to be seeking, is subject to a fee for service (\$2,363 with an opportunity to reduce the fee further if your client qualifies for a small business fee waiver) and gets a review timeline of 4 months as a M009 under the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4). Please note the interpretation language for M009 in that determinations are made for products, not substances or microorganisms, and the fee is applied per product submitted.